In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS
No. 21-1486V
Filed: March 13, 2023
PUBLISHED

TERRA RAMSEY, as mother and natural guardian of C.R. as minor,

Petitioner,

v.

SECRETARY OF HEALTH AND HUMAN SERVICES,

Respondent.

Special Master Horner

Encephalopathy; Autism; DTaP, Hib, Pneumococcal vaccines; Dismissal

Braden Andrew Blumenstiel, The Law Office of Dupont & Blumenstiel, Dublin, OH, for petitioner.
Voris Edward Johnson, U.S. Department of Justice, Washington, DC, for respondent.

DECISION[1]

On June 17, 2021, petitioner, Terra Ramsey, filed a petition under the National Childhood Vaccine Injury Act, 42 U.S.C. § 300aa-10-34 (2012),[2] alleging that C.R. suffered dizziness, loss of equilibrium, hindered motor skills, uncontrollable crying, decreased consciousness, and other neurological issues within 24 hours of his June 18, 2018 DTaP, Hib, and pneumococcal vaccinations. (ECF No. 1, pp. 1-2.) Petitioner alleges C.R. eventually received diagnoses of encephalopathy and autism. (*Id*. at 3.) For the reasons set forth below, I conclude that petitioner is not entitled to an award of compensation.

[1] Because this decision contains a reasoned explanation for the special master's action in this case, it will be posted on the United States Court of Federal Claims' website in accordance with the E-Government Act of 2002. *See* 44 U.S.C. § 3501 note (2012) (Federal Management and Promotion of Electronic Government Services). **This means the decision will be available to anyone with access to the Internet.** In accordance with Vaccine Rule 18(b), petitioner has 14 days to identify and move to redact medical or other information the disclosure of which would constitute an unwarranted invasion of privacy. If the special master, upon review, agrees that the identified material fits within this definition, it will be redacted from public access.

[2] Within this decision, all citations to § 300aa will be the relevant sections of the Vaccine Act at 42 U.S.C. § 300aa-10-34.

I. Procedural History

As noted above, petitioner alleges that C.R. was ultimately diagnosed with encephalopathy and autism spectrum disorder ("ASD"). (Ex. 5; Ex. 16, pp. 135-73.) The encephalopathy diagnosis was not indicated in the medical records filed with the petition; however, one of C.R.'s pediatricians, Carl Backes, D.O., provided a letter dated January 14, 2020, in support of petitioner's post-vaccination encephalopathy allegation. (Ex. 7; *see also* Ex. 5.)

On June 3, 2022, this case was assigned to my docket. (ECF No. 19.) On June 23, 2022, a status conference was held. I held the status conference in lieu of issuing an Initial Order to underscore to petitioner's counsel that I had serious concerns regarding the viability of this case. During the call, I discussed those concerns in detail. That discussion is memorialized in the resulting Scheduling Order of June 24, 2022. (*See* ECF No. 21.) Among other issues, I explained that

> In his letter Dr. Backes observes that C.R. had normal neurologic exams at multiple office visits on 5/04/2017, 5/19/2017, 7/20/2017, 9/20/2017, 10/05/2017, 11/07/2017, 11/13/2017, 12/14/2017, 1/19/2018, 3/15/2018, 5/04/2018, and 6/18/2018. (Ex. 7, p. 1.) He also references post-vaccination encounters of 8/3/2018 and 9/18/2018 without description, as well as a 10/26/2018 encounter at which he received a parental report apparently concerning for encephalopathy. (*Id*.)

(ECF No. 21, p. 1.) I further noted, however, that Dr. Backes' encounter records had not been filed and that "it appears there are no other contemporaneous medical records in existence that would potentially support petitioner's description of post-vaccination symptoms." (*Id*.) Moreover, "[t]he language of Dr. Backes's letter strongly suggests that C.R.'s 8/3/2018 and 9/19/2028 pediatric visits were not concerning for encephalopathy." (*Id*. at 2-3.)

The missing records were subsequently filed on August 10, 2022. (ECF No. 22; Ex. 18.) Thereafter, I issued an order on August 11, 2022, explaining that

> [b]ased on my review of the relevant records (Ex. 18, pp. 48-51), my initial interpretation of Dr. Backes's letter appears to have been correct with respect to the 8/3/2018 and 9/18/2018 encounters. Additionally, although Dr. Backes's letter indicates he received a later parental report concerning for encephalopathy at the 10/26/2018 encounter, this is not reflected in the resulting medical record. (Ex. 18, p. 47.) Dr. Backes added a diagnosis of Autism spectrum disorder to his assessment as of December 27, 2018. (*Id*. at 43.) He added "[a]dverse effect of vaccine, initial encounter" to his assessment as of January 3, 2019. (*Id*. at 42.)

(ECF No. 23, p. 1.) I ordered respondent to file his Rule 4(c) Report in 60 days if petitioner did not voluntarily dismiss the case in the interim. (*Id*. at 2.)

Respondent filed a combined Rule 4(c) Report and Motion to Dismiss on October 7, 2022. (ECF No. 24.) Respondent's report includes a complete recitation of C.R.'s medical records and explains the government's position. The government argues that Dr. Backes's diagnosis stands alone against the weight of evidence and is not credible. The government argues that this case neither meets the Vaccine Injury Table definition of encephalopathy nor satisfies the standards for finding vaccine causation-in-fact. The government stresses that "[a]t bottom, this is an autism case that is indistinguishable from past autism cases, which the special masters have uniformly dismissed." (*Id*. at 11.)

After the filing of the respondent's report, I issued an order requiring petitioner to show cause by no later than December 7, 2022, why this case should not be dismissed. (ECF No. 25.) After explaining the background of the case and the petitioner's burden of proof, I instructed petitioner to file a brief both responding to respondent's motion to dismiss and explaining pursuant to Vaccine Rule 8(d) why petitioner believes she is entitled to compensation on the existing record. (*Id*. at 3.) Alternatively, I permitted petitioner the opportunity to explain why further proceedings are reasonably necessary to develop the record and to provide an offer of proof that a credible expert report is possible. (*Id*.) I further explained that

> Petitioner's show cause response shall not be limited to a response to respondent's motion to dismiss. Even if I conclude that the petition should not be summarily dismissed as a matter of law under the standards of RCFC 12(b)(6), given that complete medical records have been filed I intend to further determine based on petitioner's show cause response whether this case is appropriate for resolution under the preponderant evidence standard based on the existing record.

(*Id*.)

Petitioner filed no response to the show cause order. Subsequently, on December 22, 2022, I issued an order noting for the record petitioner's failure to respond to the prior order to show cause and explaining that "[p]etitioner is hereby put on notice that the undersigned will issue a decision resolving this case on the existing record pursuant to Vaccine Rule 8(d)." (ECF No. 26.) I advised that if petitioner takes no action, that decision will issue on Monday, January 23, 2023. (*Id*.)

However, on January 17, 2023, petitioner filed a motion for extension of time. (ECF No. 27.) Petitioner requested 30 days "to supplement the record with additional supporting evidence (if possible) and respond to Respondent's Motion to Dismiss." (*Id*. at 1.) Petitioner's motion was granted, giving petitioner until February 17, 2023, to file a response to the order to show cause. (Order (Non-PDF), 1/17/2023.) In granting the motion I reiterated that petitioner shall file a response to my order to show cause that is not limited to responding to respondent's motion to dismiss. (*Id*.)

On February 17, 2023, petitioner filed a second motion for extension of time. (ECF No. 28.) This time petitioner requested additional time until March 10, 2023, to file a report by Dr. Shawn Aylward, C.R.'s treating neurologist. (*Id*.) Petitioner indicated that she had attempted to contact Dr. Aylward for clarification regarding the notation in his medical record that "I cannot conclusively blame this on his immunization." (*Id*. (referring to Ex. 9, p. 350).) Petitioner was reportedly informed, however, that Dr. Aylward was out of the country. Nothing in petitioner's motion suggests that petitioner actually made contact with Dr. Aylward or that he was willing to offer a report in this case. Petitioner's motion was granted, but no additional filings were made.

II. Factual History

C.R. was born on March 15, 2017, full term and without complication. (Ex. 11, p. 13.) He was generally healthy with no growth or development concerns noted during his first 15 months. On June 18, 2018, he presented for his 15-month well child encounter. (Ex. 18, p. 557.) His development was normal and he was administered the vaccines at issue in this case. (*Id*.; *see also* Ex. 1, p. 1; Ex. 5, p. 2.) According to petitioner's affidavit, C.R. began experiencing new onset of the following symptoms "shortly after" receipt of these vaccines: lethargy, dizziness and diarrhea, loss of appetite, uncontrollable crying, red and swollen injection site, tremors and body jerking, head shaking and wobbly gait, catatonic – staring off into space, and speech deterioration. (Ex. 2, p. 1.)

C.R. was next seen for medical care at his pediatrician's office on August 3, 2018, about six weeks post-vaccination. (Ex. 18, p. 51.) At that time he was seen by Dr. Backes for an ear infection. The symptoms described in petitioner's affidavit are not noted. No concern is noted regarding either encephalopathy or developmental concern. No mention is made of any vaccine reaction.

C.R.'s next medical encounter was his 18-month well child exam on September 18, 2018. (Ex. 18, pp. 452-53.) At this encounter, he saw Dr. Spitler. The interval history indicates that C.R. had no interim illnesses and that his parents had no questions or concerns. (*Id*.) Again, the symptoms listed in petitioner's affidavit were not noted and no concern for any encephalopathy was noted. Because this was a well child exam, a developmental assessment was conducted. C.R. was noted to have speech delay and a sensory food aversion. (*Id.*) Dr. Spitler referred C.R. for speech and occupational therapy and recommended that petitioner monitor C.R. closely for the next six months because "he is exhibiting some signs of autism." (*Id*. at 453.) C.R. was administered a Hepatitis A vaccination. (*Id.* at 454; Ex. 1.)

On October 2, 2018, C.R. had an occupational therapy oral motor evaluation. (Ex. 9, p. 86.) C.R. presented with "no significant medical history." (*Id*.) His prior developmental history was characterized as "[o]n target except for gross motor skills. He started off advanced with speech, then went backwards." (*Id.* at 88.) His primary encounter diagnosis was "feeding difficulties." (*Id*. at 86.) C.R. had a speech/language evaluation six days later on October 8, 2018. (*Id*. at 106.) Petitioner provided a

complete developmental history that included no description of any acute post-vaccination process or resembling an acute encephalopathy. Rather, petitioner specifically indicated that C.R. has an older brother with autism and that she is concerned he is developing similar symptoms. (*Id*. at 106-07.) C.R. was assessed as having delayed receptive and expressive language skills. (*Id*. at 107.)

C.R. returned to Dr. Backes on October 26, 2018. (Ex. 18, pp. 47, 478.)[3] Under chief complaint, C.R. was noted to be "still ill" (Ex. 18, p. 47) with symptoms of an upper respiratory infection, cough, and low-grade fever (*Id*. at 478). C.R. was assessed with a primary diagnosis of croup along with abnormal gait, speech delay, and a failed screening test. (*Id*. at 47.) The computer-generated progress note indicates C.R. developed speech delay and food texture issues in the Fall of 2018. (*Id*.) The handwritten notes additionally indicate that C.R. developed his gait abnormality "post Hep A"[4] and a developmental regression of unspecified onset. (*Id*. at 478.) There is no notation of any suspicion of a post-vaccination encephalopathy.

On November 6, 2018, C.R. was evaluated for autism and was assessed as having autism spectrum disorder ("ASD"). (Ex. 10, p. 3.) C.R.'s parents described onset of motor and speech regression at around 15 months of age. (*Id*.) Further follow up was recommended and he had a psychological evaluation on December 21, 2018. (*Id*. at 21-30.) The provided history indicates in pertinent part:

> [C.R.] appears to have unusual reactions following vaccines, including significant regression in development. [C.R.]'s speech had been developing but at about 15 months he received a vaccine and he stopped talking. He was beginning to walk appropriately, but after receiving a vaccine in September 2018, he started stumbling and his gross motor skills continue to be delayed. His mother reported that [C.R.] "acts like his right leg is paralyzed" and that his bones also "crack" often.

(*Id*. at 23.) Based on application of the Autism Diagnostic Observation Schedule, Second Edition, there was a moderate-to-severe concern that C.R. has ASD. (*Id*. at 29.)

C.R. returned to Dr. Backes on December 27, 2018, with a chief complaint of "F/u," i.e. "follow up." (Ex. 18, p. 43.) The handwritten notes for the encounter indicate a chief complaint of "limping, legs abnormal" and note onset to have been after his

[3] Two separate records exist from Kiddie West Pediatrics for C.R.'s October 26, 2018 encounter. At page 47 of Exhibit 18, a computer-generated progress note is electronically signed by Dr. Backes. At page 478 of Exhibit 18, a handwritten progress note appears to contain additional description of the same encounter. The same format holds for his later December 27, 2018 and January 3, 2019 encounters discussed below. (*Compare* Ex. 18, p. 42-43 *and,* Ex. 18, p. 498-99.)

[4] C.R. had Hepatis A vaccines administered September 18, 2018, and March 15, 2018. (Ex. 1.) Neither the petition filed in this case nor petitioner's affidavit include any allegation regarding adverse effects of C.R.'s Hepatitis A vaccinations. (ECF No. 1; Ex. 2.)

September 18, 2018 vaccination. (Ex. 18, p. 498.) The assessment was abnormal gait, developmental regression, carotenemia, and ASD. (Ex. 18, pp. 43, 498.)

C.R. again returned to Dr. Backes on January 3, 2019. The chief complaint was "discuss issue with doctor." (Ex. 18, p. 42.) Dr. Backes added "adverse effect of vaccine, initial encounter" to his assessment. (*Id*.) This time, Dr. Backes's handwritten notes indicate C.R.'s June 18, 2018 DTaP and Hib vaccines as causally relevant along with C.R.'s later September 18, 2018 Hepatitis A vaccine. (*Id.* at 499.) Genetic testing was subsequently conducted but was negative. (Ex. 9, pp. 174-77; Ex. 18, pp. 425, 433.)

C.R. was seen by a neurologist on March 12, 2019. (Ex. 9, pp. 348-50.) This time, his parents reported that the "[i]ssues all started after his last vaccine (9/18/18), which is also when mother reports he had loss of the two words he had (mamma, dadda) and social regression." (*Id*. at 348.) The neurologist opined that "[t]he workup done so far has ruled out a structural brain or peripheral nerve cause for his issues. I cannot conclusively blame this on his immunization. At this time, I would recommend they give therapy a little more time." (*Id*. at 350.)

On March 28, 2019, Dr. Backes wrote a note on a prescription pad that "[C.R.] had a [reaction] to a DTAP on 6/18/18. Within 24 hours reactions began encephalopathic." (Ex. 5, p. 1.) On January 14, 2020, Dr. Backes also wrote a "To Whom it May Concern" letter in support of petitioner's Vaccine Act claim. (Ex. 7.) In his letter, Dr. Backes writes that following C.R.'s June 18, 2018 vaccinations:

> [a]lmost immediately he was lethargic, febrile, and 'not himself' per mother. He progressed within 24 hours to shaking his head like he was dizzy and had diarrhea and loss of appetite. His DTAP injection site was red and swollen (hard) per observation of mother. Per mother over the next 48 hours his neuro status worsened – uncontrollable crying, starting off into space, head shaking, and stopped talking, stared into space and he began stumbling while walking all per mothers' observation.

(Ex. 7, p. 1.)

Dr. Backes further relates that on October 26, 2018, he "had the pleasure of a face to face exam and discussed the parental concerns of [C.R.]; I then referred [C.R.] . . . for evaluation of developmental regression and to orthopedics for his abnormal gait." (Ex. 7, p. 1.) He confirms that subsequent MRI and EMG studies were negative and that as of February 27, 2019, C.R.'s diagnosis was ASD with ongoing speech, physical, and occupational therapies. (*Id*.)

In summary, Dr. Backes writes:

> Per mother [C.R.'s] rection to the DTAP began 4 hours after the second injection and his encephalopathy signs occurred less than 72 hours post

> DTAP injection. Because of this time sequence with parental observation and the ongoing post neurological changes I am writing on his behalf to file for the Vaccine Injury Compensation Program. I am doing this now as a claim within 36-months of age with no signs of recovery from his second DTAP vaccine reaction. No VAERS was completed as this was originally done by parental observation only and concerns were not brought to my attention until 10/26/2018.

(Ex. 7, p. 2.)

III. Applicable Statutory Scheme

Under the National Vaccine Injury Compensation Program, compensation awards are made to individuals who have suffered injuries after receiving vaccines. In general, to gain an award, a petitioner must make a number of factual demonstrations, including showing that an individual received a vaccination covered by the statute; received it in the United States; suffered a serious, long-standing injury; and has received no previous award or settlement on account of the injury. Finally – and the key question in most cases under the Program – the petitioner must also establish a causal link between the vaccination and the injury. In some cases, the petitioner may simply demonstrate the occurrence of what has been called a "Table Injury." That is, it may be shown that the vaccine recipient suffered an injury of the type enumerated in the "Vaccine Injury Table," corresponding to the vaccination in question, within an applicable time period following the vaccination also specified in the Table. If so, the Table Injury is presumed to have been caused by the vaccination, and the petitioner is automatically entitled to compensation, unless it is affirmatively shown that the injury was caused by some factor other than the vaccination. § 300aa-13(a)(1)(A); § 300 aa-11(c)(1)(C)(i); § 300aa-14(a); § 300aa-13(a)(1)(B).

As relevant here, "encephalopathy" is listed on the Vaccine Injury Table relative to pertussis-containing vaccines if it occurs within 72 hours of vaccination. 42 C.F.R. § 100.3(a)(II). Table Injury cases are guided by statutory "Qualifications and Aids in interpretation" ("QAIs"), which provide more detailed explanation of what should be considered when determining whether a petitioner has actually suffered an injury listed on the Vaccine Injury Table. 42 CFR § 100.3(c).[5] In order to be considered a "Table" encephalopathy, the condition at issue must include an "acute encephalopathy" occurring within the prescribed Table window and as defined by the QAI and be followed by a "chronic encephalopathy" separately defined by the QAI. 42 CFR § 100.3(c)(2).

[5] The Vaccine Injury Table and QAI at 42 C.F.R. § 100.3 was most recently updated on January 3, 2022. The version of the Table that governs this case is the prior version that was in effect from March 21, 2017, to January 2, 2022. §300aa-14(c)(4) (explaining that modifications to the Vaccine Injury Table "shall apply only with respect to petitioners for compensation under the Program which are filed after the effective date of such regulation).

For children less than 18 months of age, an acute encephalopathy is indicated by "a significantly decreased level of consciousness that lasts at least 24 hours." *Id*. Per the QAI, the following do not in themselves demonstrate an acute encephalopathy: sleepiness, irritability or fussiness, high-pitched or unusual screaming, poor feeding, persistent inconsolable crying, bulging fontanelle, or symptoms of dementia. *Id*. Seizures are also inadequate to demonstrate an acute encephalopathy. *Id*. Under the QAI, underlying conditions or systemic diseases are exclusionary criteria that prevent an encephalopathy from being considered a Table Injury. *Id*. In general, a "chronic encephalopathy" is demonstrated where the change in mental state constituting an acute encephalopathy persists for at least six months. Where an individual returns to their baseline neurologic state prior to six months, any subsequent encephalopathy will not be presumed to be sequela of the acute encephalopathy. *Id*.

Alternatively, if no injury falling within the Table can be shown, the petitioner may still demonstrate entitlement to an award by showing that the vaccine recipient's injury or death was caused-in-fact by the vaccination in question. § 300aa-13(a)(1)(A); § 300aa-11(c)(1)(C)(ii). To so demonstrate, a petitioner must show that the vaccine was "not only [the] but-for cause of the injury but also a substantial factor in bringing about the injury." *Moberly ex rel. Moberly v. Sec'y of Health & Human Servs.*, 592 F.3d 1315, 1322 n.2 (Fed. Cir. 2010) (quoting *Shyface v. Sec'y of Health & Human Servs.*, 165 F.3d 1344, 1352–53 (Fed. Cir. 1999)); *Pafford v. Sec'y of Health & Human Servs.*, 451 F.3d 1352, 1355 (Fed. Cir. 2006). In particular, a petitioner must show by preponderant evidence: (1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a showing of proximate temporal relationship between vaccination and injury in order to prove causation-in-fact. *Althen v. Sec'y of Health & Human Servs.,* 418 F.3d 1274, 1278 (Fed. Cir. 2005).

For both Table and Non–Table claims, Vaccine Program petitioners must establish their claim by a "preponderance of the evidence". § 300aa-13(a). That is, a petitioner must present evidence sufficient to show "that the existence of a fact is more probable than its nonexistence . . . ." *Moberly*, 592 F.3d at 1322 n.2. Proof of medical certainty is not required. *Bunting v. Sec'y of Health & Human Servs.*, 931 F.2d 867, 873 (Fed. Cir. 1991). However, a petitioner may not receive a Vaccine Program award based solely on her assertions; rather, the petition must be supported by either medical records or by the opinion of a competent physician. § 300aa-13(a)(1). Once a petitioner has established their *prima facie* case, the burden then shifts to respondent to prove, also by preponderant evidence, that the alleged injury was caused by a factor unrelated to vaccination. *Althen,* 418 F.3d at 1278 (citations omitted); § 300aa-13(a)(1)(B).

IV. Legal Standard for Fact Finding

A special master must consider the record as a whole, but is not bound by any diagnosis, conclusion, judgment, test result, report, or summary concerning the nature, causation, and aggravation of petitioner's injury or illness that is contained in a medical record. §300aa-13(b)(1). However, the Federal Circuit has held that contemporaneous

medical records are ordinarily to be given significant weight due to the fact that "[t]he records contain information supplied to or by health professionals to facilitate diagnosis and treatment of medical conditions. With proper treatment hanging in the balance, accuracy has an extra premium. These records are also generally contemporaneous to the medical events." *Cucuras v. Sec'y of Health & Human Servs.*, 993 F.2d 1525, 1528 (Fed. Cir. 1993).

Thus, where medical records are clear, consistent, and complete, they should be afforded substantial weight. *Lowrie v. Sec'y of Health & Human Servs.*, No. 03-1585V, 2005 WL 6117475, at *19 (Fed. Cl. Spec. Mstr. Dec. 12, 2005). However, this rule is not absolute. Afterall, "[m]edical records are only as accurate as the person providing the information." *Parcells v. Sec'y of Health & Human Servs*., No. 03-1192V, 2006 WL 2252749, at *2 (Fed. Cl. Spec. Mstr. July 18, 2006). In *Lowrie*, the special master wrote that "written records which are, themselves, inconsistent, should be accorded less deference than those which are internally consistent." 2005 WL 6117475, at *19 (quoting *Murphy v. Sec'y of Health & Human Servs.*, 23 Cl. Ct. 726, 733 (1991), *aff'd per curiam,* 968 F.2d 1226 (Fed. Cir. 1992)). Importantly, however, "the absence of a reference to a condition or circumstance is much less significant than a reference which negates the existence of the condition or circumstance." *Murphy*, 23 Cl. Ct. at 733 (quoting the decision below), *aff'd per curiam,* 968 F.2d 1226 (Fed. Cir. 1992).

When witness testimony is offered to overcome the weight afforded to contemporaneous medical records, such testimony must be "consistent, clear, cogent, and compelling." *Camery v. Sec'y of Health & Human Servs.*, 42 Fed. Cl. 381, 391 (1998) (citing *Blutstein v. Sec'y of Health & Human Servs.*, No. 90–2808V, 1998 WL 408611, at *5 (Fed. Cl. Spec. Mstr. June 30, 1998)). Further, the Special Master must consider the credibility of the individual offering the testimony. *Andreu v. Sec'y of Health & Human Servs.*, 569 F.3d 1367, 1379 (Fed. Cir. 2009); *Bradley v. Sec'y of Health & Human Servs.*, 991 F.2d 1570, 1575 (Fed. Cir. 1993). In determining whether to afford greater weight to contemporaneous medical records or other evidence, such as testimony, there must be evidence that this decision was the result of a rational determination. *Burns v. Sec'y of Health & Human Servs.*, 3 F.3d 415, 417 (Fed. Cir. 1993). The special master is obligated to consider and compare the medical records, testimony, and all other "relevant and reliable evidence contained in the record." *La Londe v. Sec'y Health & Human Servs.*, 110 Fed. Cl. 184, 204 (2013) (citing § 12(d)(3); Vaccine Rule 8), *aff'd*, 746 F.3d 1334 (Fed. Cir. 2014); *see also Burns*, 3 F.3d at 417.

V. Discussion

a. It is appropriate to resolve this case on the existing record

The Vaccine Act and Rules not only contemplate but encourage special masters to decide petitions on the papers where (in the exercise of their discretion) they conclude that doing so will properly and fairly resolve the case. §300aa-12(d)(2)(D); Vaccine Rule 8(d). The decision to rule on the record in lieu of hearing has been affirmed on appeal. *Kreizenbeck v. Sec'y of Health & Human Servs*., 945 F.3d 1362,

1366 (Fed. Cir. 2020); *see also Hooker v. Sec'y of Health & Human Servs*., No. 02-472V, 2016 WL 3456435, at *21 n.19 (Fed. Cl. Spec. Mstr. May 19, 2016) (citing numerous cases where special masters decided case on the papers in lieu of hearing and that decision was upheld).

I do note, however, that in all events special masters must afford each party "a full and fair opportunity to present its case and create a record sufficient to allow review of the special master's decision." Vaccine Rule 3(b)(2). In this case, respondent has set forth his position in his Rule 4 Report and also included a motion to dismiss within his report. (ECF No. 24.) I subsequently issued an order to show cause providing petitioner an opportunity not only to respond to respondent's motion to dismiss, but also to present a legal brief in support of entitlement pursuant to Vaccine Rule 8(d). Moreover, I explicitly permitted petitioner to present an argument and offer of proof regarding the need for further development of the record. Following two motions for extension of time, petitioner ultimately filed no response and offered no basis upon which to conclude that any credible expert report is feasible or that further development of the record is reasonably necessary.

Accordingly, I conclude that the parties have had a full and fair opportunity to develop the record and further that resolution of this case on the existing record pursuant to Vaccine Rule 8(d) is appropriate. It is therefore not necessary to separately resolve whether respondent would otherwise be entitled to the relief under the standards applicable to his motion to dismiss.

b. Table encephalopathy

i. Acute encephalopathy

In order to establish a Table encephalopathy, petitioner must first establish that, within 72 hours of vaccination, C.R. experienced onset of an acute encephalopathy, which is "a significantly decreased level of consciousness that lasts at least 24 hours." 42 CFR § 100.3(c)(2). Per the QAI, the following do not in and of themselves demonstrate an acute encephalopathy: sleepiness, irritability or fussiness, high-pitched or unusual screaming, poor feeding, persistent inconsolable crying, bulging fontanelle, or symptoms of dementia. Rather, "[t]he symptoms associated with an acute encephalopathy are neither subtle nor insidious." *Blake v. Sec'y of Health & Human Servs*., No. 03-31V, 2014 WL 2769979, at *6 (Fed. Cl. Spec. Mstr. May 21, 2014) (quoting *Waddell v. Sec'y of Health & Human Servs*., No. 10-316V, 2012 WL 4829291, at *6 (Fed. Cl. Spec. Mstr. Sept. 19, 2012)). Acute and chronic encephalopathy is a serious injury that can necessitate hospitalization. *Miller v. Sec'y of Health & Human Servs*., No. 02-235V, 2015 WL 5456093, at *37 (Fed. Cl. Spec. Mstr. Aug. 18, 2015).

In this case, petitioner's affidavit asserts the following symptoms occurred within 24 hours of vaccination: lethargy, dizziness and diarrhea, loss of appetite, uncontrollable crying, red and swollen injection site, tremors and body jerking, head shaking and wobbly gait, catatonic – staring off into space, and speech deterioration.

(Ex. 2, p. 1.) However, this description is not supported by the medical records as delineated above. Considered as a whole, C.R.'s medical records from June of 2018 through March of 2019 reflect an evolving pattern of developmental concerns with uncertain dates of onset for specific clinical features. When comparing petitioner's affidavit with the many histories she provided to C.R.'s treating physicians, there is not preponderant evidence that C.R. experienced an acute encephalopathy within 72 hours of his pertussis-containing vaccination. To the extent petitioner's affidavit describes an abrupt onset of numerous symptoms she now asserts are concerning for an acute encephalopathy, there is no explanation to indicate why these symptoms were not the subject of prompt medical attention, why C.R. was not seen by any physician for any reason between June 18, 2018, and August 3, 2018, or why these specific symptoms were not explicitly reported at numerous subsequent medical encounters.

ii. Chronic encephalopathy

Even if petitioner had hypothetically demonstrated an acute encephalopathy, she must also demonstrate the presence of a chronic encephalopathy in order to present a Table claim. A "chronic encephalopathy" is demonstrated where the change in mental state constituting an acute encephalopathy persists for at least six months. Where an individual returns to a baseline neurologic state prior to six months, any subsequent encephalopathy will not be presumed to be sequela of the acute encephalopathy. § 100.3(d)(1)(ii).

Here, C.R. was seen at six separate medical encounters during the six months following the vaccinations at issue, including encounters with two separate pediatricians, speech and language therapy evaluations, and a psychological evaluation. None of the medical professionals he saw during this period recorded any suspicion for an encephalopathic state. Although Dr. Backes later endorsed a post-vaccination encephalopathy, he stressed that this was based on parental report *only*. (Ex. 7, p. 2.) Thus, Dr. Backes confirms that he did not observe C.R. to be encephalopathic during his encounters of August 3, 2018 and October 26, 2018, a point also reflected by his contemporaneous medical records. (*Id.*; Ex. 18, pp. 47, 51, 478.) Additionally, Dr. Backes's office colleague, Dr. Spitler, saw C.R. on September 18, 2018. (Ex. 18, pp. 452-53.) At that time, Dr. Spitler conducted a complete 18-month well exam, including developmental screening, and found no concern regarding any possible encephalopathy or altered mental state. These exams preponderantly demonstrate that, even if C.R. had experienced the post-vaccination symptoms alleged, he was back to his neurologic baseline by the time he began returning to medical care the following month, albeit the baseline of a child with developmental concerns consistent with emerging ASD. Thus, there is not preponderant evidence of a chronic encephalopathy.

c. Encephalopathy caused-in-fact by vaccination

Petitioner also has not demonstrated that C.R. suffered an encephalopathy caused-in-fact by his vaccinations. Again, although Dr. Backes endorsed a parental

report of a post-vaccination encephalopathy, the fact that he relies on parental report alone confirms that he did not observe any encephalopathic symptoms during his contemporaneous medical encounters with C.R. Nor, for that matter, did he record a diagnosis of encephalopathy in any of his actual medical treatment records. (Ex. 18.) Moreover, the fact that Dr. Backes specifies that his letter is specifically for compensation purposes and that he declined to submit a VAERS report strongly suggests that his opinion is not stated to a sufficient degree of certainty.[6] *Boatmon v. Sec'y of Health & Human Servs.,* 941 F.3d 1351, 1360 (Fed. Cir. 2019) (explaining that "[w]e have consistently rejected theories that the vaccine only 'likely caused' the injury and reiterated that a 'plausible' or 'possible' causal theory does not satisfy the standard."). Nor does Dr. Backes provide any explanation of the basis for his causal assessment. Also of note, Dr. Backes is C.R.'s pediatrician. C.R.'s neurologist, by contrast, expressed doubt that his condition was vaccine related despite also receiving a parental report of symptoms beginning post-vaccination. (Ex. 9, p. 350.)

d. Autism

A petitioner may not receive a Vaccine Program award based solely on her assertions; rather, the petition must be supported by either medical records or by the opinion of a competent physician. § 300aa-13(a)(1). Here, petitioner appears to have included in her petition an allegation that C.R. suffered vaccine-caused ASD. (ECF No. 1, p. 3.) However, neither C.R.'s medical records nor Dr. Backes's letter supporting petitioner's claim includes any suggestion that C.R.'s autism was caused by his vaccinations. Nor would such an opinion be credible if it were offered.

The question of vaccine-caused ASD has been extensively litigated both in the original Omnibus Autism Proceeding ("OAP") test cases[7] as well as in numerous

[6] VAERS is a passive reporting system where "[anyone can report an adverse event" following vaccination. *About VAERS,* HHS.GOV, https://vaers.hhs.gov/about.html (last accessed Dec. 21, 2022). It is "not designed to determine if a vaccine caused a health problems, but is [] useful for detecting unusual or expected patterns of adverse event reporting that might indicate a possible safety problem with a vaccine. *Id.; see Bender v. Sec'y of Health & Human Servs.,* No. 11-693V, 2018 WL 3679637, at *31 (Fed. Cl. Spec. Mstr. July 2, 2018) ("[b]ecause it is a passive reporting system, VAERS database findings … cannot be reasonably interpreted to suggest causation. For this reason, special masters do not typically afford great weight to VAERS data in determining causation") (citing *Analla v. Sec'y of Health & Human Servs.,* 70 Fed. Cl. 552, 558 (2006) ("the Court [of Federal Claims] uniformly has upheld the Chief Special Master's concerns about the reliability of VAERS data")). The fact that Dr. Backes specifies that the parental report he received regarding C.R.'s possible post-vaccination encephalopathy did not rise to a level of suspicion he felt would support a VAERS submission is very telling, especially given that VAERS itself disclaims any definitive causal assessment.

[7] *See Cedillo v. Sec'y of Health & Human Servs.*, No. 98-916V, 2009 WL 331968 (Fed. Cl. Spec. Mstr. Feb. 12, 2009) *aff'd*, 89 Fed. Cl. 158 (2009), *aff'd*, 617 F.3d 1328 (Fed. Cir. 2010); *Hazlehurst v. Sec'y of Health & Human Servs.*, No. 03-654V, 2009 WL 332306 (Fed. Cl. Spec. Mstr. Feb. 12, 2009), *aff'd* 88 Fed. Cl. 473 (2009), *aff'd*, 604 F.3d 1343 (Fed. Cir. 2010); *Snyder v. Sec'y of Health & Human Servs.*, No. 01-162V, 2009 WL 332044 (Fed. Cl. Spec. Mstr. Feb. 12, 2009), *aff'd*, 88 Fed. Cl. 706 (2009); *Dwyer v. Sec'y of Health & Human Servs.*, No. 03-1202V, 2010 WL 892250 (Fed. Cl. Spec. Mstr. Mar. 12, 2010); *King v. Sec'y of Health & Human Servs.*, No. 03-584V, 2010 WL 892296 (Fed. Cl. Spec. Mstr. Mar. 12,

subsequent individual cases pursuing separate theories of causation.[8] These cases have invariably been dismissed for failing to preponderantly establish a prima facie showing of causation. Although a child who happens to have ASD can still suffer a separate vaccine-related injury,[9] that is not the case here for all the reasons discussed above.

2010); *Mead v. Sec'y of Health & Human Servs.*, No. 03-215V, 2010 WL 892248 (Fed. Cl. Spec. Mstr. Mar. 12, 2010).

[8] *See*, *e.g.*, *Henderson v. Sec'y of Health & Human Servs.*, No. 09-616V, 2012 WL 5194060 (Fed. Cl. Spec. Mstr. Sept. 28, 2012) (autism not caused by pneumococcal vaccination); *Franklin v. Sec'y of Health & Human Servs.*, No. 99-855V, 2013 WL 3755954 (Fed. Cl. Spec. Mstr. May 16, 2013) (MMR and other vaccines found not to contribute to autism); *Coombs v. Sec'y of Health & Human Servs.*, No. 08-818V, 2014 WL 1677584 (Fed. Cl. Spec. Mstr. Apr. 8, 2014) (autism not caused by MMR or Varivax vaccines); *Blake v. Sec'y of Health & Human Servs.*, No. 03-31V, 2014 WL 2769979 (Fed. Cl. Spec. Mstr. May 21, 2014) (autism not caused by MMR vaccination); *Long v. Sec'y of Health & Human Servs.*, No. 08-792V, 2015 WL 1011740 (Fed. Cl. Spec. Mstr. Feb. 9, 2015) (autism not caused by influenza vaccine); *Brook v. Sec'y of Health & Human Servs.*, No. 04-405V, 2015 WL 3799646 (Fed. Cl. Spec. Mstr. May 14, 2015) (autism not caused by MMR or Varivax vaccines); *Holt v. Sec'y of Health & Human Servs.*, No. 05-136V, 2015 WL 4381588 (Fed. Cl. Spec. Mstr. June 24, 2015) (autism not caused by hepatitis B vaccine); *Lehner v. Sec'y of Health & Human Servs.*, No. 08-554V, 2015 WL 5443461 (Fed. Cl. Spec. Mstr. July 22, 2015) (autism not caused by influenza vaccine); *Miller v. Sec'y of Health & Human Servs.*, No. 02-235V, 2015 WL 5456093 (Fed. Cl. Spec. Mstr. Aug. 18, 2015) (ASD not caused by combination of vaccines); *Allen v Sec'y of Health & Human Servs.*, No. 02-1237V, 2015 WL 6160215 (Fed. Cl. Spec. Mstr. Sept. 26, 2015) (autism not caused by MMR vaccination); *R.K. v. Sec'y of Health & Human Servs.*, No. 03-632V, 2015 WL 10936124 (Fed. Cl. Spec. Mstr. Sept. 28, 2015) (autism not caused by influenza vaccine), *aff'd*, 125 Fed. Cl. 57 (2016); *Hardy v. Sec'y of Health & Human Servs.*, No. 08-108V, 2015 WL 7732603 (Fed. Cl. Spec. Mstr. Nov. 3, 2015) (autism not caused by several vaccines); *Sturdivant v. Sec'y of Health & Human Servs.*, No. 07-788V, 2016 WL 552529 (Fed. Cl. Spec. Mstr. Jan. 21, 2016) (autism not caused by Hib and Prevnar vaccines); *R.V. v. Sec'y of Health & Human Servs.*, No. 08-504V, 2016 WL 3882519 (Fed. Cl. Spec. Mstr. Feb. 19, 2016) (autism not caused by influenza vaccine) (on Court website), *aff'd*, 2016 WL 3647786 (Fed. Cl. June 2, 2016); *Murphy v. Sec'y of Health & Human Servs.*, No. 05-1063V, 2016 WL 3034047 (Fed. Cl. Spec. Mstr. Apr. 25, 2016) (autism not caused by DTaP or MMR vaccines), *aff'd*, 128 Fed. Cl. 348 (2016); *Waddell v. Sec'y of Health & Human Servs.*, No. 10-316V, 2012 WL 4829291 (Fed. Cl. Spec. Mstr. Sept. 19, 2012) (autism not caused by MMR vaccination); *Fester v. Sec'y of Health & Human Servs.*, No. 10-243V, 2016 WL 1745436 (Fed. Cl. Spec. Mstr. Apr. 7, 2016) (autism not caused by measles, mumps, rubella, and varicella (MMRV) vaccine); *Fresco v. Sec'y of Health & Human Servs.*, No. 06-469V, 2013 WL 364723 (Fed. Cl. Spec. Mstr. Jan. 7, 2013) (autism not caused by multiple vaccines); *Fesanco v. Sec'y of Health & Human Servs.*, No. 02-1770, 2010 WL 4955721 (Fed. Cl. Spec. Mstr. Nov. 9, 2010) (autism not caused by multiple vaccines); *Miller v. Sec'y of Health & Human Servs.*, No. 06-753V, 2012 WL 12507077 (Fed. Cl. Spec. Mstr. Sept. 25, 2012) (autism not caused by DTaP or MMR vaccines); *Pietrucha v. Sec'y of Health & Human Servs.*, No. 00-269V, 2014 WL 4538058 (Fed. Cl. Spec. Mstr. Aug. 22, 2014) (autism not caused by multiple vaccines); *Bushnell v. Sec'y of Health & Human Servs.*, No. 02-1648, 2015 WL 4099824 (Fed. Cl. Spec. Mstr. June 12, 2015) (autism not caused by multiple vaccines); *Bokmuller v. Sec'y of Health & Human Servs.*, No. 08-573, 2015 WL 4467162 (Fed. Cl. Spec. Mstr. June 26, 2015) (autism not caused by multiple vaccines); *Canuto v. Sec'y of Health & Human Servs.*, No. 04-1128, 2015 WL 9854939 (Fed. Cl. Spec. Mstr. Dec. 18, 2015) (autism not caused by DTP and DTaP vaccines); *Valle v. Sec'y of Health & Human Servs.*, No. 02-220V, 2016 WL 2604782 (Fed. Cl. Spec. Mstr. Apr. 13, 2016) (autism not caused by DTaP vaccine). Judges of this court have affirmed the practice of dismissal without trial in such cases. *E.g.*, *Fesanco v. Sec'y of Health & Human Servs.*, 99 Fed. Cl. 28 (2011) (Judge Braden affirming); *Canuto v. Sec'y of Health & Human Servs.*, No. 04-1128V, 2016 WL 2586510 (Judge Yock affirming).

[9] *See Wright v. Sec'y of Health & Human Servs.*, No. 12-423, 2015 WL 6665600 (Fed. Cl. Spec. Mstr. Sept. 21, 2015). Special Master Vowell concluded that a child, later diagnosed with ASD, suffered a

VI. Conclusion

Considering the record as a whole under the standards applicable in this Program, petitioner has not preponderantly established that C.R.'s June 18, 2018 vaccinations caused an encephalopathy or his ASD. Accordingly, petitioner is not entitled to compensation. Therefore, this case is dismissed.[10]

IT IS SO ORDERED.

s/Daniel T. Horner
Daniel T. Horner
Special Master

"Table Injury" after a vaccination. However, she stressed that she was *not* finding that the vaccinee's ASD in that case was "caused-in-fact" by the vaccination—to the contrary, she specifically found that the evidence in that case did *not* support a "causation-in-fact" claim, going so far as to remark that the petitioners' "causation-in-fact" theory in that case was "absurd." *Id*. at *2.

[10] In the absence of a timely-filed motion for review of this Decision, the Clerk of the Court shall enter judgment accordingly.